



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/714,887	11/13/2003	Jacqueline E. Heard	MBI-0058C1P	5720
47550 7590 11/09/2009 MENDEL BIOTECHNOLOGY C/O MOFO SF 425 MARKET STREET SAN FRANCISCO, CA 94105				
EXAMINER				
KRUSE, DAVID H				
ART UNIT		PAPER NUMBER		
1638				
MAIL DATE		DELIVERY MODE		
11/09/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/714,887

Applicant(s)

HEARD ET AL.

Examiner

David H. Kruse

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 August 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 71-79 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 71-79 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SD/US)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☒ Other: Sequence Alignment

STATUS OF THE APPLICATION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 24 August 2009 has been entered.
2. The rejections of claim 76 for indefiniteness and New Matter are withdrawn in view of Applicants' amendment and Remarks.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 71-73 and 76-79 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. At claim 71 (currently amended), lines 3-4, the limitation "comprises a first conserved domain that is at least 65% identical to amino acids 134-199 of SEQ ID NO: 4" is New Matter. Applicants' assertion that parent application 10/675,852, paragraph 0081, supports this limitation is not found to

be persuasive because said parent application make no reference to G922 (SEQ ID NO: 4), nor does it make reference to a "first conserved domain". The instant specification does not provide adequate written description support for all of the limitations in instant claim 71.

5. Claims 71-73 and 76-78 remain rejected and claim 79 is rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 26 May 2009. Applicant's arguments filed 24 August 2009 have been fully considered but they are not persuasive.

Applicants argue that have provided the polypeptide sequences G922, SEQ ID NO: 4, G3810, SEQ ID NO: 212, and G3811, SEQ ID NO: 214. Applicants argue that there are several disclosed and art-recognized alignment methods to compare two sequences. Applicants argue that the specification has taught that "[g]roups of similar genes can also be identified with pair-wise BLAST analysis" (page 52, lines 17-19). Applicants argue that the BLAST analysis has demonstrated that G3810 and G3811 are 65% and 61% identical to G922, SEQ ID NO: 4, respectively (please see attached Exhibit A). Applicants argue that an analysis by an Accelrys based method submitted with the response to a previous office action also indicates that G3810 and G3811 are 65.9% and 62.8% identical to that of G922. Applicants argue that the allegation in the

Office action that "G3811 is only 57.2% identical to SEQ ID NO: 4. [t]hus G3811 falls outside of the claimed genus" appears to have no support and all three disclosed variants G922, G3810 and G3811 share a sequence identity of at least 60% with SEQ ID NO:4. G922 has been shown to confer enhanced water deprivation tolerance when overexpressed in a plant (page 119, lines 1-3) and G3810 and G3811 also have similar function as shown in previously submitted declaration by Dr. Ratcliffe (page 5, 2nd paragraph of the Remarks). These arguments are not found to be persuasive. The Office's alignment shows a percent identity of 57.2% not 62.8%. The instant claim(s) do not set forth what method percent identity is to be used, *i.e.* there is no reference in claim 71 to an Accelrys based method. The provided alignments between G922 and G3811 are not based on the complete amino acid sequence of SEQ ID NO: 4, only amino acids 37-482.

Applicants argue that they believe that the extent of the instant disclosure in support of the claimed invention is at least commensurate with that of Example 11 in USPTO's the written description guidelines (Revision 1, March 25, 2008) where the disclosure of just two conserved domains and one singular species of the claimed genus is deemed to have met the written description requirement. Applicants argue that the instant disclosure of three conserved structural elements that are common to the claimed genus of sequences, and at least three representative functional species that have the sequence identity of at least 60% to SEQ ID NO: 4, adequately supports the claimed invention (page 5, 2nd paragraph of the Remarks). This argument is not found to be persuasive. Applicants provide no evidence of what "conserved domain" is required

to provide the specific function of the claimed genus (confers to the transgenic plant greater tolerance to water deprivation).

Applicants argue that they have provided three representative variants: G3811, G3810 and G922, which have the sequence identity of 61%, 65% and 100% to SEQ ID NO: 4, and have the function of conferring greater water deprivation tolerance to transgenic plants when overexpressed relative to controls. G3811 and G3810 are the only orthologs of G922 have been tested to date. Applicants argue that they have also disclosed the conserved structural elements, i.e. the three conserved SCR domains corresponding to amino acids 134-199, 332-401 and 405- 478 of SEQ ID NO: 4, that are always present in the sequences that have functioned by conferring water deprivation tolerance. Applicants argue that one of ordinary skill in the art would recognize that sequences having higher similarity in structure, i.e. higher than 65% to SEQ ID NO: 4 would more likely have similar functions to that of SEQ ID NO: 4 than would G3810 or G3811. Applicants argue that sequences with higher homology, for example, 80% or 95% or even greater sequence identity to SEQ ID NO: 4, could be readily made through conserved amino acid substitutions or similar amino acid substitutions, for example, the substitutions listed in Table 3 or Table 4 of the specification, outside the conserved SCR domains, and they would have the similar function to G922. Applicants argue that these disclosed polypeptide sequences having the described structure and function are derived from very diverse species, including soy and *Arabidopsis* and they represent a considerably large number of plant sequence species. Applicants argue that Applicants are not required to exemplify each and every

claimed embodiment of his or her invention. Rather, "if a person of ordinary skill in the art would have understood the inventor to have been in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then adequate written description requirement is met" (*In re Alton*, 37 USPQ2d 1578, 1584 (Fed. Cir. 1996)) (page 6, 1st paragraph of the Remarks). These arguments are not found to be persuasive. The issue of how many species Applicants have described within the claimed genus is addressed above. The domains described do not appear to describe a specific function. Table 1, at pages 35 and 36 of the instant specification identifies several "G922 orthologous", Applicants evidence only demonstrates that two of the five orthologous produce the claimed phenotype.

6. Claims 71-73 and 76-78 remain rejected and claim 79 is rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for a water deprivation tolerant transgenic plant comprising a recombinant polynucleotide that encodes SEQ ID NO: 4, does not reasonably provide enablement for a water deprivation tolerant transgenic plant comprising a recombinant polynucleotide that hybridizes to the complement of SEQ ID NO: 3. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. This rejection is repeated for the reason of record as set forth in the last Office action mailed 26 May 2009. Applicant's arguments filed 24 August 2009 have been fully considered but they are not persuasive.

Applicants argue that the specification provides a genus of sequences that are homologous to the listed sequences and share three distinct conserved SCR domains, disclosed in Table 1 beginning on page 34. Applicants argue that the fully tested G922 transcription factor family members: G922 (SEQ ID NO: 4), G3810 (SEQ ID NO: 212) and G3811 (SEQ ID NO: 214), conferred enhanced water deprivation tolerance when overexpressed in transgenic plants. Applicants argue that these sequences are derived from diverse plant species, such as Arabidopsis and soy and they represent a practical sampling of a large number of sequence species. Applicants argue that it seems unlikely that, among over 170,000 eudicot plants, Arabidopsis, the model plant being studied because of its small size, short life cycle, obligate autogamy and high fertility, and soy, the first crop species being examined, are the only plant species that have sequences that are structurally and functionally related to SEQ ID NO: 4. Applicants argue that one of ordinary skill in the art would recognize that a large number of sequences encompassed by the claims can be readily found in species that lie in the intermediate position in the evolutionary tree. Applicants argue that they have disclosed how to isolate the sequence by percent identity and similar amino acid substitution or conservative amino acid substitution (paragraph spanning pages 6-7 of the Remarks). These arguments are not found to be persuasive because Applicants have only taught how to make and use two species at the extremes of the claimed genus, said claimed genus comprising a vast number of species having the claimed "domains" but not having the claimed function.

Applicants argue that they have disclosed that the polypeptides in the claimed invention are not limited to the transcription factors or peptides that can regulate transcription. For example, page 24, lines 3-7 of the specification stated "The sequences of the present invention may be from any species, particularly plant species, in a naturally occurring form or from any source whether natural, synthetic, semi-synthetic or recombinant" and page 26, lines 1-4 stated that "[t]he present invention provides..., novel sequence variant polypeptides or polynucleotides encoding novel variants of transcription factors derived from the specific sequences provided here". Applicants argue that since they have provided the closely correlated structural elements among the claimed genus of polypeptides, i.e. having a sequence identity of at least 60% to SEQ ID NO: 4 and having a conserved domain of at least 65% identical to amino acids 134-199 of SEQ ID NO: 4, and the function of conferring improved water deprivation tolerance, it is not relevant whether the polypeptide is a true transcription factor or not. Applicants argue that one of ordinary skill in the art could readily make polynucleotide sequence variants encoding polypeptides that have the structure and function based on conservative amino acid substitutions and transform the polynucleotide sequences into plants without having to pre-determine whether the encoded polypeptides are transcription factors or not (page 7, 2nd paragraph of the Remarks). These arguments are not found to be persuasive. Applicants' statement that "the polypeptides in the claimed invention are not limited to the transcription factors or peptides that can regulate transcription" is unclear because the species Applicants' assert as being enabling are transcription factors that can regulate transcription factors.

Given Applicants have only taught how to make and use transcription factors, it would have required undue trial and error experimentation by one of skill in the art at the time of Applicants' invention to make and use non-transcription factor encoding polynucleotides to make a transgenic plant with greater tolerance to water deprivation within the full breadth of the claimed invention.

Claim Rejections - 35 USC § 103

7. Claims 71-79 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Benfey *et al* (WO 97/41152) in further view of Benfey *et al* (U.S. Patent 6,411,270, filed 24 April 1997) and Pysh *et al* (1999, The Plant Journal 18(1): 111-119). This rejection is repeated for the reason of record as set forth in the last Office action mailed 26 May 2009. Applicant's arguments filed 24 August 2009 have been fully considered but they are not persuasive.

Benfey *et al* U.S. Patent 6,411,270 is the U.S. equivalent of Benfey *et al* WO 97/41152.

The teachings of Pysh *et al* have been addressed in the Office action mailed 11 December 2007, page 9.

Applicants argue that the claims have been amended and are instantly directed to transgenic plants comprising polynucleotides that encode polypeptides that are at least 60% identical to SEQ ID NO: 4 and have three conserved domains that are highly homologous to those of SEQ ID NO: 4. Applicants argue that they have disclosed that the claimed genus of polypeptides contains the distinct SCR domains, the presence of which correlate with the claimed functions. Applicants argue that G3810, G3811 and

G922 have conserved 1st SCR domains that are at 68%, 74% and 100% to that of SEQ ID NO: 4. Applicants argue that Benfey's sequence lacks a significant portion of the protein (157 amino acid residues) and contains only 63% (42 amino acid residues out of 66 amino acid residues) of the 1st SCR domain of SEQ ID NO: 4 (page 8, 4th paragraph of the Remarks).

Applicants argue that Benfey deduces a large number of sequences by comparing the Arabidopsis SCR, SEQ ID NO: 2 in WO97/41153, with sequences in available databases (Table 1 of WO97/41153) and discloses the genus of the sequences as containing one or multiple motifs of the six conserved motifs (page 8, lines 24-30 of the Benfey publication WO9741152), these motifs are very different from the conserved SCR domains in the instant disclosure. Applicants argue that in order to determine obviousness or nonobviousness, both the claimed invention and the prior art must each be viewed as a whole. Applicants argue that in *In re Langer*, 465 F.2d 896, 175 USPQ 169 (CCPA 1972), the claims to a polymerization process using a sterically hindered amine were held unobvious over a similar prior art process because the prior art disclosed a large number of unhindered amines and only one sterically hindered amine (which differed from a claimed amine by 3 carbon atoms), and therefore the reference as a whole did not apprise the ordinary artisan of the significance of hindered amines as a class. Applicants argue that Benfey discloses a large number of sequences that lack the conserved structural elements and the claimed function, and only one species, i.e., SRPa3, whose function was yet to be confirmed, which resembles a portion of one claimed species of the instant invention, i.e. SEQ ID NO: 4. Applicants

argue that Benfey's disclosure as a whole does not apprise the ordinary artisan of the significance of the claimed genus (page 9, 1st paragraph of the Remarks). These arguments are not found to be persuasive. SEQ ID NO: 21 of Benfey is 68.2% identical to instant SEQ ID NO: 4 and comprises 63% of the first conserved domain of amino acids 134-199 of instant SEQ ID NO: 4 (see attached sequence alignment). Pysh had taught that the SCL3 (syn. SRPa3) has a tissue-specific expression pattern in the root (page 112, left column, 1st paragraph). Pysh also teaches that the mRNA encoding SCL3 is approximately 1.8kb (page 116, Figure 3 legend).

Applicants argue that the Benfey reference does not provide an enabling disclosure regarding SRPa3, SEQ ID NO: 21. Applicants argue that although Benfey suggests that SCR may confer thicker roots ("plants engineered with SCR overexpression may exhibit improved vigorous growth characteristics when cultivated under conditions where large and thicker roots are advantageous", page 154 at line 11, emphasis added), he does not provide evidence as to the function of SEQ ID NO: 21. Applicants argue that a conclusion of obviousness requires that the reference(s) relied upon be enabling in that it put the public in possession of the claimed invention (see, *In re Hoeksema*, 399 F.2d 269, 274, 158 USPQ 596, 601 (CCPA 1968)). Applicants argue that Benfey's broadly-drawn claim 18 of Benfey's publication "A plant engineered to overexpress the SCARECROW protein, so that cell division is increased in roots, resulting in thicker root development." is not enabled for plants overexpressing SRPa3, SEQ ID NO: 21 since Benfey never transformed a plant with the polynucleotide encoding SRPa3, SEQ ID NO: 21 and tested its function. Applicants argue that without

the results from rigorous experimental testing, one ordinary skill in the art would not recognize if there is a useful function associated with this sequence at all, which does not even encode a full-length protein. Applicants argue that without an enabling disclosure, one of ordinary skill in the art would not be motivated to isolate the complete coding sequence and to make transgenic plants that overexpress SRPa3, SEQ ID NO: 21 (page 7, 2nd paragraph of the Remarks). These arguments are not found to be persuasive. Benfey had taught that the SRPa3 encoding polynucleotide was partial (1.231kb), Pysh had taught that the full length mRNA is approximately 1.8kb. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. See, e.g., *In re Kahn*, 441 F.3d 977, 987, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006) (motivation question arises in the context of the general problem confronting the inventor rather than the specific problem solved by the invention). Applicants' arguments concerning an actual reduction to practice of claim 18 of Benfey is not found to be persuasive because it would have been obvious to make the invention of claim 18 of Benfey.

The statement in the Office action "it would have been obvious to isolate a complete coding region [based on the partial sequence] and transform a plant ..." is to allege that the possession of the partial sequence (SEQ ID NO: 21 of the Benfey application) also places Benfey in possession of the much longer full-length sequence (the instant SEQ ID NO: 4). Applicants argue that this assertion is inconsistent with case law teachings regarding what is required to effect possession of DNA structures. Applicants argue that in *In re Deuel*, 35 U.S.P.Q.2d 1210 (Fed. Cir. 1995), the Federal

Circuit held that claims directed to polynucleotides that encode a particular polypeptide should not be considered obvious in view of a prior art reference that taught methods of cloning, when combined with a reference that taught a partial amino acid sequence of the polypeptide. Applicants argue that the Federal Circuit stated that because the claims at issue were directed to a specific chemical structure (i.e. a nucleotide sequence), a *prima facie* case of obviousness should be based on teachings in the prior art that suggest the particular structure being claimed, irrespective of whether the methods used to arrive at the particular chemical structure were obvious. Applicants argue that the Federal Circuit noted that, "[n]ormally a *prima facie* case of obviousness is based upon structural similarity, i.e., an established structural relationship between a prior art compound and the claimed compound." Applicants argue that in the absence of such structural similarity in the prior art, the court held that a rejection based on obviousness is not proper. Applicants argue that the court in *Deuel* noted that the "...PTO's focus on known methods for potentially isolating the claimed DNA molecules is also misplaced because the claims at issue define compounds, not methods [T]he issue is the obviousness of the claimed compositions, not of the method by which they are made." Applicants argue that the Federal Circuit was clear in *Deuel* that "...the existence of a general method of isolating cDNA or DNA molecules is essentially irrelevant to the question whether the specific molecules themselves would have been obvious..." (page 10, 1st paragraph of the Remarks). These arguments are not found to be persuasive. *In re Kubin*, 90 USPQ2d 1417, 1422 (Fed. Cir. 2009) which teaches that insofar as *Deuel* implies the obviousness inquiry cannot consider that the combination of the claim's

constituent elements was "obvious to try," the Supreme Court in *KSR* unambiguously discredited that holding. In the instant case, the prior art had taught a substantial portion of the SRPa3 encoding polynucleotide, and had taught that one of ordinary skill in the art could transform a plant with a polynucleotide that encode the SRPa3 polypeptide. At the time of Applicants' invention it was routine to use a partial coding sequence to identify and isolate the complete coding sequence from an mRNA library. Given the general high level of skill in the instant art at the time of Applicants' invention, one of ordinary skill in the art would have had a reasonable expectation of success.

Applicants argue that by stating "it would have been obvious to isolate a complete coding region..." the Office action seems to argue that the method for isolating the complete sequence based on a partial sequence is available to one skilled in the art. Applicants argue that the controlling issue here is not whether the isolating the complete sequence is enabled by means of one of ordinary skill in the art, but whether Benfey envisioned/suggested the complete DNA sequence or not. Applicants argue that *Fiefs v. Sugano* and *University of California v Eli Lilly* established that possession of a DNA structure must be defined by its sequence or other physical properties. Applicants argue that this case law affirms that possession is neither defined by functionality alone nor by the availability of art-recognized means to prepare or obtain the DNA structure. Applicants argue that by analogy to chemical practice where one skilled in the art can distinguish or envisage numerous species encompassed within a generic formula, the characteristic of the 157 additional amino acids present in the complete sequence (instant SEQ ID NO: 4) must be envisaged from the structure of SEQ ID NO: 21 within

generic claim 18 of Benfey application. Applicants argue that no rational basis exists to support such an event and, therefore, no rational basis exists to support the Benfey suggests or teaches the full-length structure. Applicants argue that the illogical conclusion that a prior disclosure of the partial sequence SEQ ID NO: 21 would render the full length sequence obvious is further debunked by case law teachings of *In re Bell*, 991 F.2d 781, 26 USPQ2d 1529 (Fed. Cir. 1993), where the Federal Circuit reversed the Board's decision that Bell's claim of a nucleotide sequence is obvious over the combined teachings of the amino acid sequence encoded by the nucleotide and the method for isolating a gene for which at least a short amino acid sequence of the encoded protein is known, because "Bell claims compositions, and the issue is the obviousness of the claimed compositions, not of the method by which they are made." (page 10, 2nd paragraph of the Remarks). These arguments are not found to be persuasive. In contrast to *Fiers* or *University of California* the prior art had taught a substantial amount of the structure and the general function of the SRPa3 polypeptide. In contrast to *Bell* the prior art had taught a structure not just a method by which they are made (see *In re Kubin*).

Applicants argue that in *Fiers v. Sugano* (984 F2d 1164, 25 U.S.P.Q. 2d 1601 (Fed. Cir. 1993)), an early disclosure that lack "an intact complete gene", analogous to Benfey's disclosure on SRPa3, was deemed insufficient to support a claim on the complete gene in the later-filed application. Applicants argue that the court reiterated "[a]n adequate written description of a DNA requires more than a mere statement that it is part of the invention and a reference to a potential method for isolating it; what is

required is a description of the DNA itself." Applicants argue that Benfey's application does not describe the complete coding sequence itself, nor does it disclose a method actually leads to the DNA. It would require undue trial and error experimentation involving multiple steps, for example, RNA isolation, reverse transcription, PCR amplification, to obtain the full length cDNA sequence from the mere description of the partial sequence contained in an EST clone. Applicants argue that Benfey did not teach which method one could use to generate the complete sequence. Applicants argue that even if he did, the court teaches "A bare reference to a partial DNA with a statement that it can be obtained by reverse transcription is not a description (which Benfey does not even disclose); does not indicate ... [the] possession of the complete DNA sequence" (supra). Applicants argue that the CAFC rejected the argument that "the existence of a workable method for preparing a DNA establishes conception of that material" and stated "[o]ur statement in Amgen that conception may occur, inter alia, when one is able to define a chemical by its method of preparation requires that the DNA be claimed by its method of preparation." Applicants argue that Benfey claims the sequence itself (SEQ ID NO: 21), not by its method of preparation. Applicants argue that the CAFC stated "conception of a substance claimed per se without reference to a process requires conception of its structure, name, formula, or definitive chemical or physical properties." Applicants argue that the product, such as the complete sequence (SEQ ID NO: 4 of the instant application) is not conceived in the prior art reference until one can define it other than by its biological activity or function. Applicants argue that with an only a partial sequence that lacks one third of the coding sequence, and an

important structural domain, Benfey fails to define or suggest the complete sequence by this standard. Applicants argue that Benfey's disclosure is inadequate to put the public in possession of the invention of SEQ ID NO: 4 and thus does not render the present invention obvious (page 11, 2nd paragraph of the Remarks). These arguments are not found to be persuasive. The instant rejection is not directed to Written Description. The standard for obviousness is whether there was a reasonable expectation of success.

Applicants argue that Benfey did not transform the SRPa3 sequence into plants, nor does it provide functional data regarding the SRPa3, SEQ ID NO: 21 transgenic plants. Applicants note that Benfey's disclosure fails to teach water deprivation tolerance either expressly or implicitly. Applicants argue that regarding "[i]t would have been obvious to one of ordinary skill in the art that thicker root development would confer greater tolerance to water deprivation", Applicants respectfully disagree. Applicants argue that as one of ordinary skill in the art knows, a plant's ability to tolerate water deprivation depends on mechanisms that maintain cell water content such as osmotic regulation and stomatal closure, and is determined by multiple factors, for example, adaptations of the stomata to reduce water loss, such as reduced numbers or waxy surfaces, water storage in succulent above-ground parts or water-filled tubers, adaptations in the root system to increase water absorption, trichomes (small hairs) on the leaves to absorb atmospheric water (from: en.wikipedia.org/wiki/Drought_tolerance). Applicants argue that thicker root development alone would not necessarily account for water deprivation tolerance. Applicants argue that in Applicants' own studies, out of the twenty lines of plants transformed with SEQ ID NO: 3 encoding the full length protein

that corresponds to Benfey's partial sequence exhibited water deprivation tolerance, eighteen lines' root development is undistinguishable from the controls, and the rest two lines showed less root development than in control plants (please see the declaration by Dr. Reuber as attached). Applicants argue that this result confirmed that conferring greater tolerance to water deprivation is not obvious merely from the function of conferring thicker root development. Applicants argue that this study casts doubt on Benfey's assertion that SCARECROW proteins, which include SEQ ID NO: 21 and the corresponding full-length protein, may confer thicker roots in transgenic plants relative to controls even if the complete sequence were obtainable. Applicants argue that based on Benfey's teaching, plants that showed greater tolerance to water deprivation from Applicant's experiments would have been missed by one of ordinary skill in the art since they did not possess thicker roots relative to controls (page 12, 1st paragraph of the Remarks). These arguments are not found to be persuasive. The fact that the prior art would have made the claimed invention for a different reason is addressed above. See *Gen. Elec. Co. v Jewel Incandescent Lamp Co.*, 326 U.S. 242, 249 (1945) which teaches that it is not invention to perceive that the product which others had discovered had qualities they failed to detect; and *In re Wiseman*, 596 F.2d 1019, 1023 (CCPA 1979) which states, rejecting the notion that "a structure suggested by the prior art, and, hence, potentially in the possession of the public, is patentable...because it also possesses an inherent, but hitherto unknown, function which [patentees] claim to have discovered. This is not the law. A patent on such a structure would remove from the

public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art.

Conclusion

8. No claims are allowed.
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (571) 272-0799. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at (571) 272-0975. The central FAX number for official correspondence is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (571) 272-1600.

/David H Kruse/
Primary Examiner, Art Unit 1638
5 November 2009